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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/518,842 | 03/03/2000 | Stephen R Jaspers | 96-41D1 | 7571 |

7590

06/30/2003

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EXAMINER

BUNNER, BRIDGET E

ART UNIT

PAPER NUMBER

1647

15

DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/518,842

Applicant(s)

JASPERS ET AL.

Examiner

Bridget E. Bunner

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6-15 is/are pending in the application.
- 4a) Of the above claim(s) 6-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☒ Claim(s) 1-3 and 6-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

- **DETAILED ACTION**

Status of Application, Amendments and/or Claims

The amendment of 22 April 2002 (Paper No. 10) has been entered in full. Claim 1 is amended and claims 4-5 are cancelled.

This application contains claims 6-15 drawn to an invention nonelected without traverse in Paper No. 5 (19 June 2001). A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3 are under consideration in the instant application.

Withdrawn Objections and/or Rejections

1. The objection to the declaration at pg 2-3 of the previous Office Action (Paper No. 6, 17 July 2001) is *withdrawn* in view of the submitted substitute declaration (Paper No. 14, 18 November 2002).
2. The objections to the specification at pg 3-4 of the previous Office Action (Paper No. 6, 17 July 2002) are *withdrawn* in view of the amended specification and title (Paper No. 10, 22 April 2002).
3. The objections to claims 4-5 at pg 4 of the previous Office Action (Paper No. 6, 17 July 2001) are *withdrawn* in view of the cancelled claims (Paper No. 10, 22 April 2002). Please see section on Claim Objections, below.

Art Unit: 1647

4. The rejection of claims 1-3 under 35 U.S.C. § 101 as set forth at pg 4 of the previous Office Action (Paper No. 6, 17 July 2001) is *withdrawn* in view of the amendments to the claims recite the term "isolated" (Paper No. 10, 22 April 2002).

5. The rejection of claims 1-5 under 35 U.S.C. § 112, first paragraph (Paper No. 6, 17 July 2001) is *withdrawn* in view of the cancelled claims and Applicant's persuasive arguments (Paper No. 10, 22 April 2002).

6. The rejections of claims 4-5 under 35 U.S.C. 112, second paragraph, as set forth at pg 7-8 of the previous Office Action (Paper No. 6, 17 July 2001) are *withdrawn* in view of the cancelled claims (Paper No. 10, 22 April 2002).

7. The rejection of claims 3-5 under 35 U.S.C. § 102(b) as set forth at pg 8 of the previous Office Action (Paper No. 6, 17 July 2001) is *withdrawn* in view of the cancelled claims and Applicant's persuasive arguments (Paper No. 10, 22 April 2002). Please see section on 35 U.S.C. § 102(b), below.

Drawings

8. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Objections

9. Claim 3 is objected to because of the following informalities:

9a. Claim 3 is objected to as being dependent upon a rejected base claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

10. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Chassin et al. (Genomics 29: 465-470, 1995).

Chassin et al. teaches an isolated protein encoded by a DNA segment encoding a nucleotide sequence shown in SEQ ID NO: 1 from nucleotide 76 to 417 (see pg 467, Figure 1; see also sequence alignment attached to this Office Action as Appendix A).

Applicant's arguments (Paper No. 10, 22 April 2002), as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

Applicant asserts that Chassin et al. describes a sequence of nucleotides and amino acids encoded therefrom that include a signal peptide (numbers -1 to -17) and an intron/exon structure which constitutes the human INSL4 gene. Applicant argues that while there is similarity in the overall sequences, the structure of the protein is very different and does not anticipate the present invention. Applicant contends that the present invention claims a protein shorter by eight amino acid residues at the N-terminus than the Chassin et al. polypeptide because the secretory signal sequence in the instant application is predicted to be longer, ending at residue 25 (Ala), rather than residue 17 (Ser) as predicted by Chassin et al. Applicant states that nowhere in Chassin et al. is a mature protein of 114 amino acids taught. Applicant submits that Figure 2 of Chassin et al. teaches that based on the authors' structural analysis, the mature polypeptide N-terminus is at residue 18, and while the present inventors expressed, sequenced and identified certain activities associated with the claimed protein, the references do not suggest the EPIL was ever even expressed to verify their predictions.

Applicant's arguments have been fully considered but are not found to be persuasive. Specifically, the claims are drawn to an isolated protein produced by a method comprising culturing a host cell into which has been expressed a DNA expression vector that comprises a DNA segment *comprising* a nucleotide sequence shown in SEQ ID NO: 1 from nucleotide 76 to nucleotide 417. The term "comprising" is open-ended language and does not exclude additional, unrecited elements (see MPEP § 2111.03). Therefore, although the EPIL protein of Chassin et al. is predicted to be longer than 114 amino acids, the claimed protein of the instant application is still disclosed by Chassin et al. since it is encompassed within the larger sequence due the phrase "DNA segment comprising" recited in the claims. (Please note that this issue could be overcome by amending the claims to recite "DNA segment *consisting* of a nucleotide sequence...".)

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:30-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9305.

Elizabeth C. Kemmerer

BEB
Art Unit 1647
June 23, 2003

ELIZABETH KEMMERER
PRIMARY EXAMINER